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(54) A DEVICE FOR MOUNTING A PROSTHESIS ON SKELETAL TISSUE

(71) We, AGA AKTIEBOLAG, a Swedish Company, of Lidingö, Sweden, do hereby declare the invention, for which we pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement:—

If a device for mounting a prosthesis of natural or artificial material is implanted, or embedded, in a human body, or in any other biologically living material, it requires to be fixed either permanently or at least for a given period of time, during which it may become firmly attached to its selected place in the organism. The prosthesis may be of many different kinds, for instance leg prostheses, articulation prostheses and so forth, but the most typical, or most widely used, implantation device is that required for permanently mounting a dental prosthesis. The present invention relates to a device which serves for mounting such a prosthesis and which itself is permanently implantable in a bone or other skeletal tissue existing in the organism.

Various permanently implantable mounting devices of this type are already known, but in many instances they have proved unsatisfactory because they may be subject to a rejection process of the human body as a result of which the implanted device (below generally, for the sake of simplicity, called "prosthesis", even if it does not form such a prosthesis in a strict sense), will cease to perform its intended function and will lose its bond with the organism. In other instances, the purely mechanical design and construction of the devices have been such that they could not reliably be expected to remain bonded to the organism and, in fact, have frequently shown a tendency to detach themselves.

When devices for mounting prostheses are implanted, such implantation is usually effected in skeletal tissue of the body. Thus, a surgical incision into the skeletal tissue as well as into the weak epithelial tissue situated outside the former is unavoidable. If, therefore, a tooth prosthesis has to be attached by means of such a device, it becomes necessary to uncover the jaw-bone for which purpose it is essential to cut through connective tissue as well as the gums. It has been found that it is difficult for the resulting wounds in the skeletal and the weak epithelial tissue to heal if the prosthesis is attached to the device during the healing period. Likewise, it is also very difficult to provide a good connection between the device and the skeletal tissue if the prosthesis is attached to the former during the healing period. In order to overcome these difficulties, it has already been proposed to separate the fixing device from the prosthesis proper, and first to implant the device, suitable for the purpose, into the bone or the skeletal tissue, then to leave the device in the incision and to permit the bone and tissue to heal, and to attach thereafter, *i.e.* after the skeletal tissue, and the bones, have healed completely, or at least reasonably completely, and have formed a bond with the device, the prosthesis to the device.

In order to render such a procedure possible, it is necessary for the device to project from the skeletal tissue as well as from the weak tissue by a distance sufficient to permit attachment of the prosthesis thereto. However, it has been proved that if the device projects healing of the tissues is considerably more difficult and, as a result, less thorough because the projecting part of the fixing device will, during the healing period when it does not yet carry the prosthesis proper, be subjected to mechanical stresses which may interfere with the healing process of the tissues. Moreover, the healing wound may also be infected from the outer surroundings through the passage formed by a perforated part of the device. It will be clear, therefore, that healing can take place under essentially more favourable conditions if the fixing, or mounting, device is completely embedded in the weak tissue and/or the skeletal tissue during the healing period. However, as previously implied, difficulties

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will then arise in connection with securing the prosthesis to the device.

The present invention aims at overcoming, or at least minimizing, these difficulties and accordingly provides a device for mounting a prosthesis on skeletal tissue, comprising a two-part spacing member and a substantially hollow embedding member insertable into a cavity in the skeletal tissue such that it is completely embedded therein, the embedding member including an innermost part locatable in the innermost portion of the cavity and an outermost part removably securable to the innermost part and exchangeable by the spacing member which is also securable to said innermost part of the embedding member, the spacing member being provided with means for securing the prosthesis thereto.

Further details of the invention will be evident from the following description of some embodiments of the invention; however, it is understood that the invention shall not be limited to these embodiments, but that different kinds of modifications may be effected within the scope of the invention.

In the drawings,

Figure 1 shows an embedding member of a device according to the invention to be inserted into a cavity in skeletal tissue;

Figure 2 shows a spacing member securable to the embedding member and being the member the greater part of which is situated above the skeletal and weak tissues, and to which the prosthesis is intended to be attached; as these two members comprise a plurality of components, and are removably securable to each other, they have in both figures been shown in so-called exploded projection;

Figure 3 shows the embedding member according to Figure 1 during healing of the tissues;

Figure 4 shows the embedding member according to Figure 1 after completed healing with the spacing member according to Figure 2 secured thereto;

Figure 5 shows a different embodiment of the embedding member; and

Figure 6 shows a spacing member securable thereto.

In the arrangement illustrated in Figure 1, an embedding member of a mounting device according to the invention comprises a substantially hollow bolt 10 which is externally threaded. These threads are intended to be screwed into a bored and threaded cavity in the jaw-bone for permanent implantation of the embedding member for the purpose of mounting a denture, or dental prosthesis. The bolt is bored from one end to form a well, or aperture, 11, and holes 12 run from the sides through the threads into the well 11 in a direction normal to the longitudinal extent thereof. The bolt section tapers downwardly at 13. The hollow of the member 10 also comprises at the end portion opposite the well 11 a well 14 which is internally threaded for a purpose which will be evident from the following. For screwing the bolt into the jaw-bone a screw driver groove 15 is arranged in the edge of the well 14. A dividing wall 16 is provided between the two wells 11 and 14.

As already indicated, the bolt is intended to serve as an embedding member locatable in the innermost portion of the cavity and to which, later on, a spacing member as shown in Figure 2 is to be secured. This, however, should not take place until the skeletal tissue in the jaw-bone has healed and, further, has formed an integrating growth around and through the bolt 10. The holes 12 are provided to promote this integrating growth therethrough. Newly formed skeletal tissue will thus get an opportunity to grow into the holes 12 so that unscrewing of the bolt is effectively prevented. The external surface of the bolt including external thread should further be treated in such a way that it will be somewhat rough and/or porous; this roughening of the surface can be effected by, for instance, etching, blasting, knurling or the like. Thus, healing producing integrating growth between the skeletal tissue and the bolt is further promoted.

It may be assumed that if separated loose skeletal tissue material exists in the interior of the well 11, this may also promote, during tissue healing, such an integrating growth of the tissue through the holes 12. Such loose material will be scraped off the bulk of the skeletal tissue while the bolt 10 is screwed into the cavity, and this scraping is due to the cutting, or scraping, action of sharp edges of the holes 12 and to the fact that the bolt, as already mentioned, tapers downwardly as indicated at 13. Each of these factors produces a certain amount of tissue scrapings, and the scraped tissue will be driven through the holes 12 into the well 11.

The bolt 10 forms the innermost part of the embedding member which is also provided with a tightening device, or outermost part to be removably secured to the bolt during the healing period. A ring 17 functions as such a tightening device; it is applied to an upper part, or flange, 18 of the bolt which, for this purpose, is shaped slightly conically. The ring is provided at its lower end with a sharp edge 19 the purpose of which is to enter, when applying the ring 17 to the bolt 10, into the bottom of a small recess around the upper edge of the cavity which has been bored in the jaw-bone to accommodate the bolt 10. As a result of the edge 19 "biting" into the bottom of the recess a seal is created, by means of which impurities or non-desired weak tissue may effectively be prevented from entering into

the cavity in the jaw-bone which would adversely affect healing. The ring 17 is secured to the bolt 10—and will remain attached thereto throughout the healing period—by means of a screw, or bolt, 20 threaded to mesh with the internal threads in the well 14. The head of said screw tightly contacts an inclined flange 21 on the ring.

In the foregoing description a sequence of steps for applying the embedding member has been described calling for the innermost part, or bolt, 10 to be screwed first into the cavity in the jaw-bone and for the ring 17 thereafter to be attached thereto by means of the screw 20. Of course, the sequence may be thus, but in practice it may in many instances be more advantageous to proceed differently, *i.e.* to assemble the bolt 10, the ring 17 and the screw 20 first into a single unit, comprising all of these three elements, and to implant this unit in the cavity in the jaw-bone. The unit is shown in this state in Figure 3.

It should remain in this state shown in Figure 3 during all of the tissue-healing period which may vary between some weeks and some months, depending upon the circumstances of each specific case. Weak tissue, which initially covers jaw-bone, and which will be folded away when the cavity in the jaw-bone is prepared, will be replaced by sutures or in some other suitable way above the embedding member so that it will be completely covered. Thus it will be well protected throughout all of the healing period against mechanical, chemical and bacteriological effects, and the tissue healing will take place without disturbance.

After healing is completed, the weak tissue above the ring 17 and the screw 20 will be cut away so that these parts are uncovered. The ring 17 and the screw 20 will then be removed. They will be replaced by a spacing member shown in Figure 2. It comprises, in the embodiment illustrated, a sleeve 22, which is also provided with a sharp edge 23 for the same purpose as the edge 19 on the ring 17 previously mentioned. The configuration of the sleeve 22 at its lower end portion corresponds as exactly as possible to the configuration of the lower end portion of the ring 17 so that the lower end portion of the sleeve will be completely adapted to the recess in the tissue cavity exposed when the ring is removed. The sleeve 22 finally is secured by means of a screw or bolt, 24, which is externally threaded for engagement with the internal threads in the well 14 in the bolt 10; the bolt 24 is also provided with an internally threaded bore, the internal thread serving for securing the prosthesis to the spacing and embedding members. The attachment should be such that no relative turning movement between the spacing member and the bolt of the embedding member will occur at a later stage. The complete arrangement will then look as illustrated in Figure 4. A screw driver groove 25 is arranged for screwing in the screw 24.

It has already been mentioned that, preferably, the bolt 10 be provided by some suitable or convenient means, with a rough and/or porous surface in order to promote growth of the tissue, during healing, for the purpose of integrating it with the bolt. Certain other elements, however, should as far as possible be prevented from being integrated with the tissue. This applies especially with respect to the ring 17, which should only be used temporarily during the healing period and which after the tissue has healed will be replaced by the spacing member. It also concerns the sleeve 22 except its lowermost end portion at which a given tissue attachment may be desired. The parts which are not desired to be attached to or integrated by the tissue during the healing period should be smooth.

The choice of the material for the different elements is of exceedingly great importance. There are many different materials from which a device according to the present invention could be produced but there are still more materials which are completely unsuitable for the purpose. The suitable materials are called tissue compatible, because neither the skeletal tissue nor the weak tissue shows any tendency of rejecting them. Thus, the material should be chemically as well as biologically compatible with the tissue. However, one has also to take account of many other requirements which a material for a device according to the invention, particularly the embedding member, must meet, of which the following ones should be mentioned.

For natural reasons the embedding member will be of very small dimensions. Nevertheless, it must be capable of retaining the prosthesis even when subjected to rather heavy stresses. This means that the embedding member should have a very high rigidity. It must further be substantially immune against ageing. The embedding member in spite of being so small must be finished to a high degree of accuracy, which calls for easy workability of the material of which it is to be made. Finally, the material must be chemically inert against all ingredients in food as well as the materials existing in the mouth cavity, and against all kinds of bacteriological attacks.

Some metallic alloys are known, closely related to stainless steel, which satisfy these requirements, and further there are some tissue compatible plastics which satisfy them. The best material hitherto known, however, certainly is pure or weakly alloyed titanium. It is well known in surgery that titanium

has favourable properties in the above mentioned respects.

The above considerations will apply in the first instance to the choice of material for the bolt, or innermost part, 10, which will be permanently attached to the jaw-bone. The ring 17, however, may be made from some other material, if this material possesses a given elasticity or plasticity, so that it will easily adapt itself to the jaw-bone, this is only to be regarded as an advantage, because thereby its sealing function will in some cases be improved.

Instead of titanium one may use some other metal for the elements previously stated to be made from titanium, said other metal then to be coated with titanium, for instance by a galvanic process.

It is not necessary that the cavity provided in the jaw-bone be internally threaded, or that the inwardly tapering part of the bolt 10 of the embedding members be threaded externally, even if one can thus obtain an extremely good bond between the jaw-bone and the embedding member. Indeed, one may also obtain a good bond with the bored cavity without the latter being threaded, for instance if the innermost part of the embedding member is so wide that it requires to be squeezed into the hole; however, it should not, of course, be so wide that it will crack the jaw-bone or cause fissures therein when pressed down into the cavity. The external surface of the bolt may, in this instance, be smooth but not slippery, and it may be provided with barb-like grooves or projections which permit the bolt to be inserted into but prevent it from being drawn out from the cavity.

Another possibility of embedding of the bolt in the cavity is shown in Figures 5 and 6. As in the embodiment previously described the bolt 10 is provided with a number of holes, for instance four such holes, leading into the hollow, or wall, 11. The end portion of the bolt below these holes 12, however, is slotted, the number of slots being such that a number of tongues 27 corresponding to the number of holes 12 are formed.

The inner surfaces of the tongues 27 taper inwardly and downwardly. A disc 28 is inserted into the hollow 11 and rests therein on the edge formed between its straight portion and its tapering end portion said disc being so dimensioned that a sliding fit is provided between it and the inner wall of the straight portion of the well 11. Now, a screw 29 having a pin-shaped projection 30 is screwed into the internal threads in the bolt 10, which in this case is provided with a threaded through-hole extending through its whole length, until the projection 30 contacts the disc 28, and thereafter the bolt 10 is embedded into the cavity bored in the jaw-bone. The screw 29 will then be tightened so that its projection 30 will press the disc 28 between the inwardly tapering tongues 27, and these are forced to expand outwardly. A very strong and good bond may thus be obtained.

The specific advantage with this arrangement is that it eliminates the need of boring, from opposite ends, two wells 11 and 14 (see Figure 1) into the bolt 10. Instead, a single hollow, or through-bore, may be used. The dividing wall 16 in this case will be replaced by the screw 29.

In another respect too the arrangement according to Figures 5 and 6 differs from the previously described embodiment. In the arrangement shown in Figures 1 and 2, sealing against the ingress of impurities from outside is substantially obtained by the sharp edge 19 on the ring 17 attached to the bolt 10 during the healing period and thereafter by a corresponding sharp edge 23 on the sleeve 22 of the spacing member. In the arrangement according to Figure 6 one has instead provided the bolt with a flange 35 which carries on its lower side such a sharp edge 31. The flange 35 includes an upper surface 32 intended to carry the lower end face of the sleeve 22 of the spacing member. The bolt 24 of the spacing member corresponds exactly to that illustrated in Figure 2.

When the embedding member is implanted, it must be completely pure and sterile. Usual sterilization methods have in some cases not proved sufficient for this purpose. Preferably, one should use especially highly effective cleaning and sterilization methods, such as subjecting the member to ultra sonic waves of high power, in combination with the application of chemically active cleaning and sterilizing agents.

It is important that there should not be any gap between the lower end portion, or end face, of the spacing member and the respective bolt flange in contact therewith. In the arrangement illustrated in Figures 1 and 2 this is achieved as a result of providing the sleeve 22 with an internal end portion which tapers inwardly from the end face and which matches the taper on the peripheral wall of the flange 18 of the bolt 10. In the arrangement shown in Figures 5 and 6 the lower end face of the sleeve 22 is exactly adapted to the shape of the upper surface 32 of the flange 35 on the bolt 10. Both arrangements provide a good seal.

This seal, however, is liable to be impaired if the spacing member is subjected to any disturbing mechanical impact in sideward direction, for instance, as a result of a blow to the jaw. Thus, it is important to damp such stresses by interposing between the prosthesis and the bolt a material which is sufficiently elastically resilient. For that reason the screw, or bolt, 24 of the spacing

member is made of some suitable elastic material, *e.g.* plastics. Moreover, it is provided with a small neck 33 of a diameter smaller than that of the remaining part of the bolt 24 for increasing the elastic resiliency. If the prosthesis is subjected to a very strong lateral impact, the bolt may even be broken at its neck 33 so that the connection between the bolt 10 and the spacing member will cease. It is then usually an easy matter to remove the prosthesis and to replace the spacing member by a new one without injury to the jaw bone.

In order that the spacing member should have the required freedom of movement without its sleeve 22 following any such movement and transferring such movement to the bolt, or innermost part, 10, a gap 34 is provided all around between the sleeve 22 and the screw 24.

The sleeve 22 should be made of metal, preferably for the above mentioned reasons, of titanium. This should be polished so that it is bright in its upper part for preventing impurities from attaching to its surface. However, it is desirable that the surface of its end portion close to the bolt 10 has a finish of the same kind as the surface of said bolt to facilitate integrating tissue growth.

There are tissues sensitive to heat and cold in the jaw-bone. Therefore it is also important that the prosthesis be heat insulated from the jaw-bone. If the elements of the embedding member are made throughout from metal, a heat conduction bridge will be produced, which could cause temperature shocks in the tissue, for instance when consuming a hot or a cold drink. It is advisable, therefore, to interpose in a suitable place in this heat-conduction bridge a material of low heat conductivity in order to interrupt this bridge. Thus, it is especially advantageous if the bolt 24 is made of some heat insulating plastics. Most plastics having the desired elasticity for damping mechanical impacts are also well suited for damping heat shocks of the said kind.

Although the invention has been described with reference to a device for mounting a denture, it is to be understood that it is not restricted to this particular purpose but is equally applicable for mounting other prostheses.

WHAT WE CLAIM IS:—

1. A device for mounting a prosthesis on skeletal tissue, comprising a two-part spacing member and a substantially hollow embedding member insertable into a cavity in the skeletal tissue such that it is completely embedded therein, the embedding member including an innermost part locatable in the innermost portion of the cavity and an outermost part removably securable to the innermost part and exchangeable by the spacing member which is also securable to said innermost part of the embedding member, the spacing member being provided with means for securing the prosthesis thereto.

2. A device according to Claim 1, wherein the outermost part of the embedding member and the spacing member each include an end portion which when they are secured to the innermost part is adjacent thereto, and wherein the configuration of the two end portions is substantially the same.

3. A device according to Claim 1 or Claim 2, wherein the external surface of the innermost part of the embedding member is treated to facilitate its adhesion to skeletal tissue.

4. A device according to Claim 3, wherein the external surface of the outermost part of the embedding member is smooth to minimise its adhesion to skeletal tissue.

5. A device according to any of the preceding claims, wherein the hollow of the innermost part of the embedding member at its end portion locatable closest to the innermost portion of the cavity includes an aperture shaped to permit ingrowth of skeletal tissue.

6. A device according to any of the preceding claims, wherein the innermost part of the embedding member is provided at its end portion closest to the outermost part with a flange, and wherein the outermost part and the spacing member, respectively, abut the flange when secured to the innermost part.

7. A device according to any of the preceding claims, wherein the hollow of the innermost part of the embedding member includes a threaded hole arranged to receive a bolt for securing the outermost part and the spacing member, respectively, to the innermost part.

8. A device according to any of the Claims 1 to 4 or Claim 6 when dependent on any of the Claims 1 to 4, wherein the hollow of the innermost part of the embedding member is an internally threaded through-bore, wherein the through-bore tapers inwardly at its inner end portion locatable closest to the innermost portion of the cavity, and wherein a bolt insertable into the threaded bore is arranged to cooperate with the tapered end portion, the arrangement being such that in operation tightening of the bolt in the bore will cause the inner end portion of the innermost part to expand into the skeletal cavity.

9. A device according to Claim 8, wherein the outer end portion of the threaded through-bore opposite its inner end portion is arranged to receive a bolt for securing the outermost part and the spacing member, respectively, to the innermost part.

10. A device according to any of the

Claims 1 to 7, wherein the innermost part of the embedding member is externally threaded for screwing it into the cavity provided in the skeletal tissue.

11. A device according to Claim 10, wherein the innermost part of the embedding member is provided with holes extending in a direction normal to its hollow to permit growth of skeletal tissue thereinto, the edges of said holes being sufficiently sharp to cut away portions of the skeletal tissue when in operation the innermost part is screwed into the cavity.

12. A device according to Claim 7 or any of the Claims 10 or 11, wherein the threaded hole is separated from the aperture by a dividing wall.

13. A device according to any of the preceding claims, wherein the one part of the spacing member is a sleeve while the other part is a bolt partly located within the sleeve and adapted to secure it to the innermost part of the embedding member and being internally threaded, the internal thread forming the means for securing the prosthesis to the spacing and embodding members.

14. A device according to Claim 13, wherein the bolt is made of a resilient material.

15. A device according to Claim 13 or Claim 14, wherein the internal diameter of the sleeve is larger than the external diameter of the portion of the bolt located therein.

16. A device according to any of the Claims 13 to 15, wherein the bolt is provided with a neck of a diameter smaller than that of the remaining part of the bolt, the arrangement being such that in the event of the spacing member, or the prosthesis respectively, being subjected to a lateral impact the bolt will break rather than said member or prosthesis.

17. A device according to any of the Claims 13 to 16, wherein one of the elements of the spacing member is made of a heat-insulating material.

18. A device for mounting a prosthesis on skeletal tissue, constructed, arranged and adapted to operate substantially as herein described with reference to Figures 1 to 4 and 5 to 6 respectively of the accompanying drawings.

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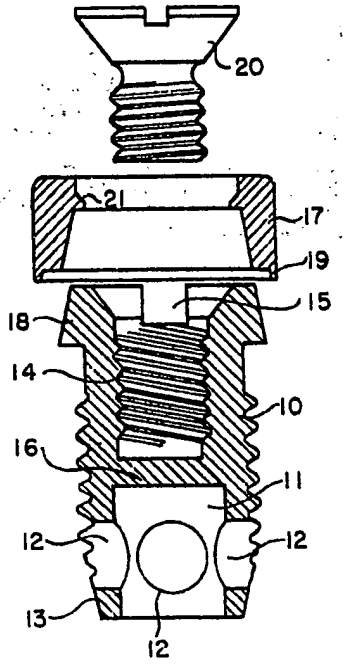
Fig.1



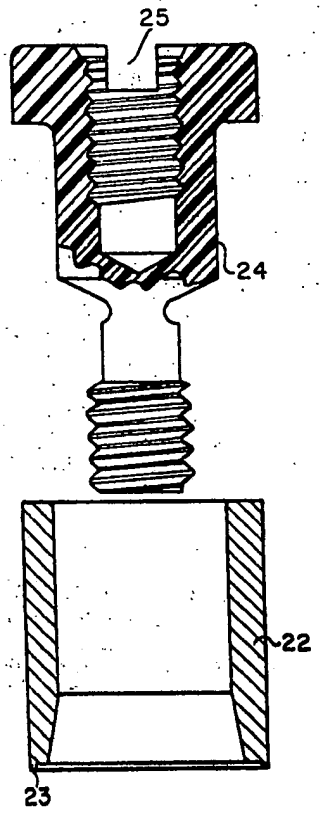


Fig.2

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Fig. 4

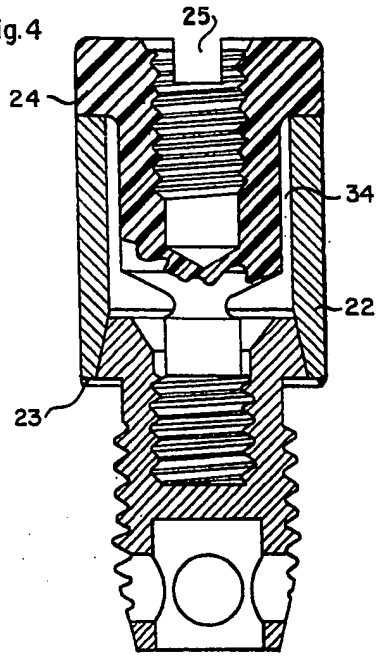

Fig. 3.

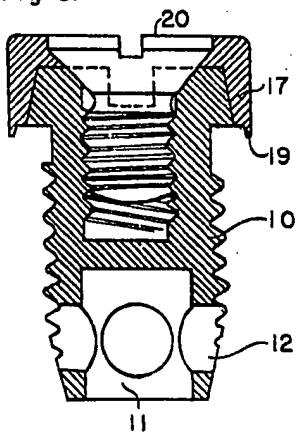

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Fig.6

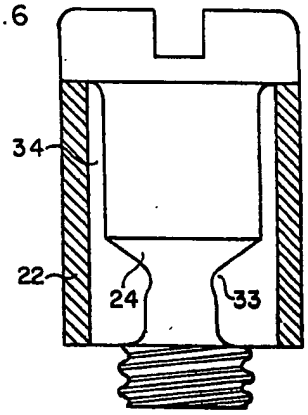

Fig.5